

Date published: 17 September, 2024 Date last updated: 17 September, 2024

Managing conflicts of interest in the NHS

Publication (/publication)

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Scope of this guidance

This guidance is intended to protect patients, taxpayers and staff and to cover health services in which there is a direct state interest.

It replaces and updates the NHS-wide guidance 'Managing conflicts of interest in the NHS', issued in 2017, to take account of changes introduced by the Health and Care Act 2022, specifically the establishment of integrated care boards and the introduction of the provider selection regime.

It is applicable to the following NHS bodies:

- integrated care boards (ICBs)
- NHS trusts (all or most of whose hospitals, establishments and facilities are situated in England) and NHS foundation trusts – which include secondary care trusts, mental health trusts, community trusts, and ambulance trusts
- NHS England

For the purposes of this guidance these bodies are referred to as 'organisations'.

ICBs should be aware of their duties under the National Health Service Act 2006 (as amended) for managing conflicts of interest, including the requirement for them to establish and maintain their policy and register. The guidance on ICB governance (ICB issued by NHS England recommends principles for ICBs in drafting their conflicts of interest policy. NHS England is making available conflicts of interest training for ICBs.

NHS trusts and NHS foundation trusts must have regard to this guidance through its incorporation into the NHS Standard Contract pursuant to general condition 27. NHS trusts and NHS foundation trusts are also expected to comply with the trust Code of governance-for-nhs-provider-trusts/#appendix-c-the-code-and-other-regulatory-requirements). While this guidance applies in its entirety to NHS trust and foundation trust employees, the Code of governance makes additional provisions about conflicts of interest that are specific to employees of NHS trusts and foundation trusts. If the wording of the 2 guidance documents differs on a particular point, the Code of governance should take precedence.

NHS trusts and foundation trusts and ICBs should also have regard to the statutory guidance on arrangements for delegation and joint working (https://www.england.nhs.uk/long-read/arrangements-for-delegation-and-joint-exercise-of-statutory-functions/) which contains information about managing conflicts of interest when organisations are using new powers to work in an integrated way.

This guidance also applies to NHS England and its staff through our <u>Standards of business conduct policy (https://www.england.nhs.uk/publication/standards-of-business-conduct-policy/)</u>.

This guidance does not apply to bodies not listed above (ie independent and private sector organisations, general practices, social enterprises, community pharmacies, community dental practices, optical providers, local authorities – who are subject to different legislative and governance requirements). However, the boards/governing bodies of these organisations are invited to consider implementing the guidance as a means to effectively manage conflicts of interest and provide safeguards for their staff. The requirements of GC27.2 of the generic NHS Standard Contract (https://www.england.nhs.uk/nhs-standard-contract/24-25/) should be interpreted in that light.

1. Purpose

1.1 Guidance purpose

Every year the taxpayer entrusts NHS organisations with over £190 billion to care for millions of people. This money must be spent well, free from undue influence.

The Health and Care Act 2022 (**the Act**) gave integrated care systems (**ICSs**) legal underpinning, with integrated care boards being established as statutory bodies with legal powers and responsibilities. The Act signalled a clear shift in the way health and care is organised in England and better enables organisations to work collaboratively with each other, local authorities, industry and other public, private and voluntary bodies. Partnership working is fundamental if we are to meet challenges faced by the health and care sector, but conflicts of interest must still be carefully managed to maintain the confidence and protect the interests of patients and taxpayers.

Organisations and the people who work with, for, and on behalf of them (referred to as 'staff' in this guidance) want to manage these risks in the right way. For clarity, references to 'staff' in this document include those who are not employees but have a formal role in organisational decision-making, in particular board and sub-/committee members.

By implementing this guidance staff and organisations will understand what to do to take the best action and protect themselves from allegations that they have acted inappropriately.

This guidance:

- sets out consistent principles and rules for managing conflicts of interest
- provides simple advice to staff and organisations about what to do in common situations
- supports good judgement about how interests should be approached and managed

2. Action

2.1 Actions for staff

Do:

 familiarise yourself with this guidance and your organisational policies and follow them

- use your common sense and judgement to consider whether the interests you have could affect the way taxpayers' money is spent
- regularly consider what interests you have and declare these as they arise.
 If in doubt, declare

Don't:

- misuse your position to further your own interests or the interests of those close to you
- be influenced, or give the impression that you have been influenced, by outside interests
- allow outside interests that you hold to inappropriately affect the decisions you make about spending taxpayers' money

2.2 Actions for organisations

Do:

- ensure that you have clear and well communicated processes in place to help staff understand what they need to do
- identify a team or individual with responsibility for:
 - o reviewing current policies and bringing them in line with this guidance
 - providing advice, training and support for staff on how interests should be managed
 - maintaining register(s) of interests
 - auditing policy, process and procedures relating to this guidance at least every 3 years

Don't:

- avoid managing conflicts of interest
- interpret and deploy this guidance in a way that stifles the collaboration and innovation that the NHS needs

Organisations should ensure their policies as a minimum meet the standards in this guidance. They can also introduce local requirements that are more stringent, on the basis of their own circumstances, should they think this is necessary.

3. Definitions

3.1 Definition: conflict of interest

For the purposes of this guidance a 'conflict of interest' is defined as:

"A set of circumstances by which a reasonable person would consider that an individual's ability to apply judgement or act, in the context of delivering, commissioning, or assuring taxpayer funded health and care services is, or could be, impaired or influenced by another interest they hold".

A conflict of interest may be:

- actual there is a material conflict between 1 or more interests
- potential there is the possibility of a material conflict between 1 or more interests in the future

Staff may hold interests for which they cannot see any potential conflict. However, caution is always advisable because others may see it differently. It will be important to exercise judgement and to declare such interests where there is otherwise a risk of imputation of improper conduct.

3.2 Definition: interests

'Interests' can arise in a number of different contexts. A material interest is one which a reasonable person would take into account when making a decision regarding the use of taxpayers' money because the interest has relevance to that decision.

A benefit may arise from the making of a gain or the avoidance of a loss.

Financial interest – where an individual may get direct financial benefit from the consequences of a decision they are involved in making.

Non-financial professional interests – where an individual may obtain a non-financial professional benefit from the consequences of a decision they are involved in making, such as increasing their professional reputation or promoting their professional career.

Non-financial personal interests – where an individual may benefit personally in ways which are not directly linked to their professional career and do not give rise to a direct financial benefit, because of decisions they are involved in making in their professional career.

Indirect interests – where an individual has a close association with another individual who has a financial interest, a non-financial professional interest or a non-financial personal interest who would stand to benefit from a decision they are involved in making. These associations may arise through relationships with close family members and relatives, close friends and associates, and business partners. A common-sense approach should be applied to these terms. It would

be unrealistic to expect staff to know of all the interests that people in these classes might hold. However, if staff do know of material interests (or could be reasonably expected to know about these) then these should be declared.

Further guidance on how to interpret these categories can be found in <u>annex A</u>.

4. Declarations

4.1 Processes to follow

Organisations should support staff to understand that having interests is not in itself negative, but not declaring and managing them is.

All staff must be aware of how and to whom declarations should be made, declaring material interests at the earliest opportunity (and in any event within 28 days) via a positive declaration to their organisation. Therefore, declarations should be made:

- on appointment with an organisation
- when a person moves to a new role or their responsibilities change significantly
- at the beginning of a new project/piece of work
- as soon as circumstances change and new interests arise.

Some staff are more likely than others to have a decision-making influence on the use of taxpayers' money, because of the requirements of their role. For the purposes of this guidance these people are referred to as 'decision-making staff'.

Because of their influence in the spending of taxpayers' money, organisations should ensure that decision-making staff are prompted to update their declarations of interest or make a nil return, at least annually.

Organisations should define decision-making staff according to their own context, but this should be justifiable and capture those groups of staff that have a material influence on how taxpayers' money is spent.

The following non-exhaustive list describes who these individuals are likely to be:

executive and non-executive directors who have decision-making roles
which involve the spending of taxpayers' money (equivalent roles in different
organisations carry different titles and these should be considered on a
case-by-case basis)

- members of advisory groups which contribute to direct or delegated decision-making on the commissioning or provision of taxpayer-funded services
- those at Agenda for Change band 8D and above (reflecting <u>guidance</u> (https://ico.org.uk/for-organisations/foi/publication-schemes-a-guide/definition-documents/) issued by the Information Commissioner's Office with regard to freedom of information legislation)
- administrative and clinical staff who have the power to enter into contracts on behalf of their organisation
- administrative and clerical staff involved in decision-making concerning the commissioning of services, purchasing of goods, medicines, medical devices or equipment and formulary decisions.

There may be occasions where staff declare an interest but upon closer consideration it is clear that this is not material and so does not give rise to the risk of a conflict of interest. The team or individual responsible for managing organisational policy should decide whether it is necessary to transfer such declarations to an organisation's register(s) of interests.

5. Management

5.1 Principles and situations

Organisations should manage interests sensibly and proportionately. If an interest presents an actual or potential conflict of interest then management action is required.

Some common-sense management principles should be adopted by organisations which, for the purposes of this guidance, are referred to as 'general management actions':

- requiring staff to comply with this guidance
- requiring staff to proactively declare interests at the point they become involved in decision-making
- considering a range of actions, which may include:
 - deciding that no action is warranted
 - restricting an individual's involvement in discussions and excluding them from decision-making
 - removing an individual from the whole decision-making process
 - removing an individual's responsibility for a whole area of work
 - removing an individual from their role altogether if the conflict is so significant that they are unable to operate effectively in the role
- keeping an audit trail of actions taken

Each case will be different. The general management actions, along with relevant industry/professional guidance should complement the exercise of good judgement. It will always be appropriate to clarify circumstances with individuals involved to assess issues and risks.

However, there are a number of common situations which can give rise to risk of conflicts of interest, these being:

- · gifts
- hospitality
- outside employment
- shareholdings and other ownership interests
- patents
- loyalty interests
- donations
- sponsored events
- sponsored research
- sponsored posts
- clinical private practice

The next section discusses the risks and issues posed in these situations, and the principles and rules that staff and organisations should adopt to manage them.

5.2 Examples of situations

Gifts

Issues

Staff in the NHS offer support during significant events in people's lives. For this work they may sometimes receive gifts as a legitimate expression of gratitude. We should be proud that our services are so valued. But situations where the acceptance of gifts could give rise to conflicts of interest should be avoided. Staff and organisations should be mindful that even gifts of a small value may give rise to perceptions of impropriety and might influence behaviour if not handled in an appropriate way.

A gift means any item of cash or goods, or any service, which is provided for personal benefit, free of charge, or at less than its commercial value.

Principles and rules

Overarching principle applying in all circumstances:

 staff should not accept gifts that may affect, or be seen to affect, their professional judgement

Gifts from suppliers or contractors:

- gifts from suppliers or contractors doing business (or likely to do business)
 with an organisation should be declined, whatever their value
- subject to this, low-cost branded promotional aids may be accepted where
 they are under the value of a common industry standard of £6 in total and
 need not be declared. The £6 value has been selected with reference to the
 Association of the British Pharmaceutical Industry's (ABPI) Code of practice
 for the pharmaceutical industry 2021
 (https://www.abpi.org.uk/publications/code-of-practice-for-thepharmaceutical-industry-2021/).

Gifts from other sources (eg patients, families, service users):

- gifts of cash and vouchers should always be declined
- staff should not ask for any gifts, regardless of value
- gifts valued at over £50 should be treated with caution and only be accepted
 on behalf of an organisation (ie to an organisation's charitable funds), not in
 a personal capacity. Staff should declare such gifts and provide a clear
 reason as to why it was considered permissible to accept the gift, alongside
 the actual or estimated value
- modest gifts under a value of £50 do not need to be declared
- a common-sense approach should be applied to the valuing of gifts (using an actual amount, if known, or an estimate that a reasonable person would make as to its value)
- multiple gifts from the same source over a 12-month period should be treated in the same way as single gifts over £50 where the cumulative value exceeds £50

What should be declared?

- staff name and their role with the organisation
- a description of the nature and value of the gift
- date of receipt
- any other relevant information (eg circumstances surrounding the gift, action taken to mitigate against a conflict, details of any approvals given to depart from the terms of this guidance)

Hospitality

Issues

Delivery of services across the NHS relies on working with a wide range of partners (including industry and academia) in different places and, sometimes, outside of 'traditional' working hours. As a result, staff will sometimes appropriately receive hospitality. Staff receiving hospitality should always be prepared to justify why it has been accepted and be mindful that even hospitality of a small value may give rise to perceptions of impropriety and might influence behaviour.

Hospitality means offers of meals, refreshments, travel, accommodation, and other expenses in relation to attendance at meetings, conferences, education and training events, etc.

Principles and rules

Overarching principle applying in all circumstances:

- staff should not ask for or accept hospitality that may affect, or be seen to affect, their professional judgement
- hospitality must only be accepted when there is a legitimate business reason and it is proportionate to the nature and purpose of the event
- particular caution should be exercised when hospitality is offered by actual
 or potential suppliers or contractors these can be accepted if modest and
 reasonable but individuals should always obtain senior approval and declare
 these

Meals and refreshments:

- under a value of £25 may be accepted and need not be declared
- of a value between £25 and £75 may be accepted and must be declared.
 The £75 value has been selected with reference to existing industry
 guidance (https://www.abpi.org.uk/reputation/abpi-2021-code-of-practice/)
 issued by the ABPI
- over a value of £75 should be refused unless (in exceptional circumstances) senior approval is given. A clear reason should be recorded on an organisation's register(s) of interest as to why it was permissible to accept
- a common-sense approach should be applied to the valuing of meals and refreshments (using an actual amount, if known, or an estimate that a reasonable person would make as to its value)

Travel and accommodation:

 modest offers to pay some or all of the travel and accommodation costs related to attendance may be accepted and must be declared

- offers which go beyond modest or are of a type that the organisation might not usually offer, need approval by senior staff, should only be accepted in exceptional circumstances, and must be declared. A clear reason should be recorded on an organisation's register(s) of interest as to why it was permissible to accept travel and accommodation of this type
- A non-exhaustive list of examples includes:
 - offers of business class or first-class travel and accommodation (including domestic travel)
 - offers of foreign travel and accommodation

What should be declared?

- staff name and their role with the organisation
- a description of the nature and value of the hospitality including the circumstances
- date of receipt
- any other relevant information (eg action taken to mitigate against a conflict, details of any approvals given to depart from the terms of this guidance)

Outside employment

Issues

The NHS relies on staff with good skills, broad knowledge and diverse experience. Many staff bring expertise from sectors outside the NHS, such as industry, business, education, government and beyond. The involvement of staff in these outside roles alongside their NHS role can therefore be of benefit, but the existence of these should be well known so that conflicts can be either managed or avoided.

Outside employment means employment and other engagements, outside of formal employment arrangements. This can include directorships, non-executive roles, self-employment, consultancy work, charitable trustee roles, political roles and roles within not-for-profit organisations, paid advisory positions and paid honorariums which relate to bodies likely to do business with an organisation. (Clinical private practice is considered in a separate section).

Principles and rules

- staff should declare any existing outside employment on appointment, and any new outside employment when it arises
- where a risk of conflict of interest is identified, the general management actions outlined in this guidance should be considered and applied to mitigate risks

- where contracts of employment or terms and conditions of engagement permit, staff may be required to seek prior approval from an organisation to engage in outside employment
- organisations may also have legitimate reasons within employment law for knowing about outside employment of staff, even this does not give rise to risk of a conflict. Nothing in this guidance prevents such enquiries being made

What should be declared?

- staff name and their role with the organisation
- a description of the nature of the outside employment (eg who it is with, a description of duties, time commitment)
- relevant dates
- any other relevant information (eg action taken to mitigate against a conflict, details of any approvals given to depart from the terms of this guidance)

Shareholding and other ownership interests

Issues

Holding shares or other ownership interests can be a common way for staff to invest their personal time and money to seek a return on investment. However, conflicts of interest can arise when staff personally benefit from this investment because of their role with an organisation. For instance, if they are involved in their organisation's procurement of products or services which are offered by a company they have shares in then this could give rise to a conflict of interest. In these cases, the existence of such interests should be well known so that they can be effectively managed.

Principles and rules

- staff should declare, as a minimum, any shareholdings and other ownership interests in any publicly listed, private or not-for-profit company, business, partnership or consultancy which is doing, or might be reasonably expected to do, business with their organisation
- there is no need to declare shares or securities held in collective investment or pension funds or units of authorised unit trusts
- where shareholdings or other ownership interests are declared and give rise to risk of conflicts of interest then the general management actions outlined in this guidance should be considered and applied to mitigate the risks

- staff name and their role with the organisation
- a description of the nature of the shareholding/other ownership interest
- · relevant dates
- any other relevant information (eg action taken to mitigate against a conflict, details of any approvals given to depart from the terms of this guidance)

Patents

Issues

The development and holding of patents and other intellectual property rights allows staff to protect something that they create, preventing unauthorised use of products or the copying of protected ideas. Staff are encouraged to be innovative in their practice and therefore this activity is welcomed.

However, conflicts of interest can arise when staff who hold patents and other intellectual property rights are involved in decision making and procurement. In addition, where product development involves use of time, equipment or resources from their organisation, then this too could create risks of conflicts of interest, and it is important that the organisation is aware of this and it can be managed appropriately.

Principles and rules

- staff should declare patents and other intellectual property rights they hold (either individually, or by virtue of their association with a commercial or other organisation), including where applications to protect have started or are ongoing, which are, or might be reasonably expected to, related to items to be procured or used by their organisation
- staff should seek prior permission from their organisation before entering into any agreement with bodies regarding product development, research, work on pathways, etc, where this impacts on the organisation's own time, or uses its equipment, resources or intellectual property
- where holding of patents and other intellectual property rights give rise to a conflict of interest then the general management actions outlined in this guidance should be considered and applied to mitigate risks

- staff name and their role with the organisation
- a description of the patent or other intellectual property right and its ownership
- relevant dates.

• any other relevant information (eg action taken to mitigate against a conflict, details of any approvals given to depart from the terms of this guidance)

Loyalty interests

Issues

As part of their jobs, staff need to build strong relationships with colleagues across the NHS and in other sectors. These relationships can be hard to define as they may often fall in the category of indirect interests. They are unlikely to be directed by any formal process or managed via any contractual means – it can be as simple as having informal access to people in senior positions. However, loyalty interests can influence decision making.

Conflicts of interest can arise when decision making is influenced subjectively through association with colleagues or organisations out of loyalty to the relationship they have, rather than through an objective process. The scope of loyalty interests is potentially huge, so judgement is required for making declarations.

Principles and rules

Loyalty interests should be declared by staff involved in decision-making where they:

- hold a position of authority in another NHS organisation or commercial, charity, voluntary, professional, statutory or other body which could be seen to influence decisions they take in their NHS role
- sit on advisory groups or other paid or unpaid decision-making forums that can influence how their organisation spends taxpayers' money
- are, or could be, involved in the recruitment or management of close family members and relatives, close friends and associates, and business partners
- are aware that their organisation does business with an organisation with whom close family members and relatives, close friends and associates, and business partners have decision making responsibilities
- where holding loyalty interests gives rise to a conflict of interest then the general management actions outlined in this guidance should be considered and applied to mitigate risks

- staff name and their role with the organisation
- a description of the loyalty interest
- · relevant dates

• any other relevant information (eg action taken to mitigate against a conflict, details of any approvals given to depart from the terms of this guidance)

Donations

Issues

A donation is a charitable financial payment, which can be in the form of direct cash payment or through the application of a will or similar directive. Charitable giving and other donations are often used to support the provision of health and care services. As a major public sector employer the NHS holds formal and informal partnerships with national and local charities. Staff will, in their private lives, undertake voluntary work or fundraising activities for charity. A supportive environment across the NHS and charitable sector should be promoted. However, conflicts of interest can arise.

Principles and rules

- donations made by suppliers or bodies seeking to do business with an
 organisation should be treated with caution and not routinely accepted. In
 exceptional circumstances a donation from a supplier may be accepted but
 should always be declared. A clear reason should be recorded as to why it
 was deemed acceptable, alongside the actual or estimated value
- staff should not actively solicit charitable donations unless this is a
 prescribed or expected part of their duties for an organisation or is being
 pursued on behalf of that organisation's registered charity (if it has one) or
 other charitable body and is not for their own personal gain
- staff must obtain permission from their organisation if in their professional role they intend to undertake fundraising activities on behalf of a preapproved charitable campaign.
- Donations, when received, should be made to a specific charitable fund (never to an individual) and a receipt should be issued
- staff wishing to make a donation to a charitable fund in lieu of a professional fee they receive may do so, subject to ensuring that they take personal responsibility for ensuring that any tax liabilities related to such donations are properly discharged and accounted for

What should be declared?

 organisations should maintain records in line with their wider obligations under charity law, in line with the above principles and rules

Sponsored events

Issues

Sponsorship of NHS events by external parties is valued. Offers to meet some or part of the costs of running an event secures their ability to take place, benefiting NHS staff and patients. Without this funding there may be fewer opportunities for learning, development and partnership working. However, there is potential for conflicts of interest between the organiser and the sponsor, particularly regarding the ability to market commercial products or services. As a result, there should be proper safeguards in place to prevent conflicts occurring.

Principles and rules

- sponsorship of events by appropriate external bodies should only be approved if a reasonable person would conclude that the event will result in clear benefit for the organisation and the NHS
- during dealings with sponsors there must be no breach of patient or individual confidentiality or data protection rules and legislation
- no information should be supplied to the sponsor from which they could gain a commercial advantage, and information which is not in the public domain should not normally be supplied
- at an organisation's discretion, sponsors or their representatives may attend
 or take part in the event but they should not have a dominant influence over
 the content or the main purpose of the event
- the involvement of a sponsor in an event should always be clearly identified in the interest of transparency
- organisations should make it clear that sponsorship does not equate to endorsement of a company or its products and this should be made visibly clear on any promotional or other materials relating to the event
- staff should declare involvement with arranging sponsored events to their organisation

What should be declared?

 organisations should maintain records regarding sponsored events in line with the above principles and rules

Sponsored research

Issues

Research is vital in helping the NHS to transform services and improve outcomes. Without sponsorship of research some beneficial projects might not happen. More broadly, partnerships between the NHS and external bodies on research are important for driving innovation and sharing best practice. However,

there is potential for conflicts of interest to occur, particularly when research funding by external bodies does or could lead to a real or perceived commercial advantage. There needs to be transparency and any conflicts of interest should be well managed.

Principles and rules

- funding sources for research must be transparent
- any proposed research must go through the relevant health research authority or other approvals process
- there must be a written protocol and written contract between staff, the
 organisation, and/or institutes at which the study will take place and the
 sponsoring organisation, which specifies the nature of the services to be
 provided and the payment for those services
- the study must not constitute an inducement to prescribe, supply, administer, recommend, buy or sell any medicine, medical device, equipment or service
- staff should declare involvement with sponsored research to their organisation

What should be declared?

- organisations should retain written records of research sponsorship in line with the above principles and rules
- staff should declare:
 - their name and their role with the organisation
 - a description of the nature of the nature of their involvement in the sponsored research
 - relevant dates
 - any other relevant information (eg what, if any, benefit the sponsor derives from the sponsorship, action taken to mitigate against a conflict, details of any approvals given to depart from the terms of this guidance)

Sponsored posts

Issues

Sponsored posts are positions with an organisation that are funded, in whole or in part, by organisations external to the NHS. Sponsored posts can offer benefits to the delivery of care, providing expertise, extra capacity and capability that might not otherwise exist if funding was required to be used from the NHS budget. However, safeguards are required to ensure that the deployment of sponsored posts does not cause a conflict of interest between the aims of the sponsor and the aims of the organisation, particularly in relation to procurement.

Principles and rules

- staff who are establishing the external sponsorship of a post should seek formal prior approval from their organisation
- rolling sponsorship of posts should be avoided unless appropriate checkpoints are put in place to review and confirm the appropriateness of arrangements continuing
- sponsorship of a post should only happen where there is written
 confirmation that the arrangements will have no effect on purchasing
 decisions or prescribing and dispensing habits. For the duration of the
 sponsorship, auditing arrangements should be established to ensure this is
 the case. Written agreements should detail the circumstances under which
 organisations have the ability to exit sponsorship arrangements if conflicts of
 interest which cannot be managed arise
- sponsored post holders must not promote or favour the sponsor's specific products, and information about alternative products and suppliers should be provided
- sponsors should not have any undue influence over the duties of the post or have any preferential access to services, materials or intellectual property relating to or developed in connection with the sponsored posts

What should be declared?

 organisations should maintain records regarding sponsored events in line with the above principles and rules

Clinical private practice

Issues

Service delivery in the NHS is done by a mix of public, private and not-for-profit organisations. The expertise of clinicians in the NHS is in high demand across all sectors and the NHS relies on the flexibility that the public, private and not-for-profit sectors can provide. It is therefore not uncommon for clinical staff to provide NHS funded care and undertake private practice work either for an external company, or through a corporate vehicle established by themselves.

Existing provisions in contractual arrangements make allowances for this to happen and professional conduct rules apply. However, these arrangements do create the possibility for conflicts of interest arising. Therefore, these provisions are designed to ensure the existence of private practice is known so that potential conflicts of interest can be managed. These provisions around declarations of activities are equivalent to what is asked of all staff in the section on outside/employment.

Principles and rules

Clinical staff should declare all private practice on appointment, and/or any new private practice when it arises including:

- where they practise (name of private facility)
- what they practise (specialty, major procedures)
- when they practise (identified sessions/time commitment)
- hospital consultants are already required to provide their employer with this information by virtue of paragraph 3, schedule. 9 of <u>Terms and conditions</u> – <u>consultants (England) (https://www.nhsemployers.org/articles/consultantcontract-2003)</u>

Clinical staff should (unless existing contractual provisions require otherwise or unless emergency treatment for private patients is needed):

- seek prior approval of their organisation before taking up private practice
- ensure that, where there would otherwise be a conflict or potential conflict of interest, NHS commitments take precedence over private work (these provisions already apply to hospital consultants by virtue of paragraphs 5 and 20, schedule 9 of the Terms and conditions consultants (England) (https://www.nhsemployers.org/articles/consultant-contract-2003)
- · not accept direct or indirect financial incentives from private providers

Hospital consultants should not initiate discussions about providing their private professional services for NHS patients, nor should they ask other staff to initiate such discussions on their behalf (these provisions already apply to hospital consultants by virtue of paragraphs 5 and 20, schedule 9 of the Terms and conditions - consultants (England)

(https://www.nhsemployers.org/articles/consultant-contract-2003)).

Where clinical private practice gives rise to a conflict of interest then the general management actions outlined in this guidance should be considered and applied to mitigate risks.

- staff name and their role with the organisation
- a description of the nature of the private practice (eg what, where and when you practise, sessional activity, etc)
- relevant dates
- any other relevant information (eg action taken to mitigate against a conflict, details of any approvals given to depart from the terms of this guidance)

5.3 Strategic decision-making groups

Many organisations use boards (or committees and sub-committees of boards), advisory groups and procurement panels to make key strategic decisions or recommendations about things such as:

- entering into (or renewing) large scale contracts
- · awarding contracts
- making procurement decisions
- · selection of medicines, equipment and devices

These are referred to in this guidance as 'strategic decision-making groups'.

It is important that the interests of those who are involved in these groups are documented and understood. Organisations must therefore identify relevant strategic decision-making groups and ensure they operate in a manner consistent with the following principles, which reflect wider standards of good governance:

- chairs should consider any known interests of members in advance and begin each meeting with a standing agenda item asking for declarations of relevant interests
- members should take personal responsibility for declaring material interests at the beginning of each meeting and as they arise
- any new interests identified should be added to the organisation's register
- the vice-chair (or other non-conflicted member) should chair all or part of the meeting if the chair has an interest that may prejudice their judgement
- terms of reference for such groups should refer to the organisation's policy and procedures for managing conflicts of interest and should set out any specific requirements which apply to the group

If a member has an actual or potential interest the chair should consider the following approaches and ensure that the reason for the chosen action is documented in minutes or records:

- requiring the member to not attend the meeting
- ensuring that the member does not receive meeting papers relating to the nature of their interest
- requiring the member to not attend all or part of the discussion and decision on the related matter
- noting the nature and extent of the interest, but judging it appropriate to allow the member to remain and participate
- remove the member from the group or process altogether

The default response should not always be to exclude members with interests, as this may have a detrimental effect on the quality of the decision being made. An example is the need for clinical involvement, when clinicians may hold and represent a diversity of interests. Good judgement is required to ensure proportionate management of risk. The composition of groups should be kept under review to ensure effective participation.

5.4 Procurement decisions

Procurement should be managed in an open and transparent manner, compliant with procurement and other relevant law. Procurement processes should be conducted in the best interest of patients.

Organisations should keep records that show a clear audit trail of how conflicts of interest have been identified and managed as part of procurement processes. At every stage of procurement, steps should be taken to identify and manage conflicts of interest to ensure and to protect the integrity of the process.

The provider selection regime (PSR) came into force on 1 January 2024. The PSR is a set of rules for procuring health services which are designed to be a more flexible and proportionate decision-making process for selecting providers to deliver healthcare services.

Organisations[1] need to comply with the PSR when arranging for the provision of "relevant health care services,"[2] either on their own or as part of a "mixed procurement"[3].

Organisations need to take appropriate measures to effectively prevent, identify and remedy conflicts of interest arising in the conduct of procurement processes under The Health Care Services (Provider Selection Regime) Regulations 2023 ('PSR Regulations'). The definition of conflicts of interest for the purposes of the PSR is set out in regulation 21(2)(a) of the PSR Regulations[4]. Integrated care board (ICBs) should note the specific carve-out from this definition in regulation 21(3) relating to ICB board members. Further information about the PSR, including about the management of conflicts of interest, can be found within the PSR statutory guidance (https://www.england.nhs.uk/publication/the-provider-selection-regime-statutory-guidance/).

Organisations need to comply with the rules on public procurement set out in the Public Contracts Regulations 2015 ('PCR') when arranging for the provision of goods and services that are not "relevant health care services", unless they form part of a "mixed procurement," which meets the test for the application of the PSR.

The Procurement Act 2023 ('Procurement Act') is expected to come into force later in 2024, at which point it will replace the PCR. Organisations will need to take all reasonable steps to identify, and keep under review, in relation to any procurement under the Procurement Act any conflicts of interest or potential conflicts of interest. "Conflict of interest" is defined for the purposes of the Procurement Act in Section 81. The Procurement Act will impose new duties on organisations with regards to the assessment and management of conflicts of interest[5].

For the avoidance of doubt, nothing in this section or this guidance waives or modifies any existing legal requirements relating to conflicts of interest and procurement decisions.

- [1] NHS England, integrated care boards, NHS trusts and foundation trusts, local authorities and combined authorities are defined as "relevant authorities" for the purposes of the PSR.
- [2] See regulation 2(1) of The Health Care Services (Provider Selection Regime) Regulations 2023
- [3] See Regulation 3(2) of The Health Care Services (Provider Selection Regime) Regulations 2023
- [4] This definition is substantively the same as the definition of conflicts of interest contained in the Public Contracts Regulations 2015 (Regulation 24(2)).
- [5] See for example Sections 82 and 83.

6. Transparency

6.1 Maintenance of register(s)

Organisations must ensure that a nominated team or individual collates and maintains up to date organisational register(s) of interests. An interest should remain on the register(s) for a minimum of 6 months after the interest has expired. Organisations should retain a private record of historic interests for a minimum of 6 years after the date on which it expired.

Template declaration of interests and register of interests forms should always contain:

- the returnee's name and their role with the organisation
- a description of the interest declared (reflecting the content of section 5 of this guidance for common situations)

- relevant dates relating to the interest
- space for comments (eg action taken to mitigate conflict)

Using a common format in the templates will help minimise burdens on staff who might need to submit returns to multiple organisations.

6.2 Publication

All staff should declare interests and, as a minimum, organisations should publish the interests of decision-making staff at least annually in a prominent place on their website. Organisations without websites should maintain registers locally, available for inspection on request.

The format of published registers should be accessible and contain meaningful information. Adopting the templates and advice on content in this guidance will assist organisations in this task.

Organisations should put in place processes for staff to make representations that information on their interests should not be published. This will allow for, in exceptional circumstances, an individual's name and/or other information to be redacted from any publicly available registers where the public disclosure of information could give risk to a real risk harm or is prohibited by law.

As well as taking these steps, organisations should seek to ensure that staff who are subject to wider transparency initiatives, such as the <u>Association of the British Pharmaceutical Industry (ABPI) Disclosure UK scheme (https://www.abpi.org.uk/reputation/disclosure-uk/)</u>, are aware of and comply with them.

7. Breaches

7.1 How to deal with breaches

There will be situations when interests will not be identified, declared or managed appropriately and effectively. This may happen innocently, accidentally, or because of the deliberate actions of staff or organisations. For the purposes of this guidance, these situations are referred to as 'breaches'.

Organisations should identify a team or individual to be notified of breaches and be clear as to how staff or other parties can raise concerns about these. Staff should be encouraged to speak up about actual or suspected breaches, in compliance with their organisation's whistleblowing policy.

Organisations should also identify a team or individual empowered to investigate breaches, involving organisational leads for human resources, fraud, audit etc, as appropriate. Each breach needs to be investigated and judged on its own merits and this should start with those involved having the opportunity to explain and clarify any relevant circumstances.

Following investigations, organisations should:

- decide if there has been or is potential for an actual breach and the severity
- assess whether further action is required in response this is likely to involve any staff member involved and their line manager, as a minimum
- consider who else inside and outside the organisation should be made aware of the breach
- take appropriate action, such as clarifying existing policy, taking action against the staff member(s) responsible for the breach, or escalating to external parties such as auditors, the NHS Counter Fraud Authority, the Police, statutory health bodies and/or regulatory bodies

When dealing with instances of breach, organisations may want to take legal or other appropriate advice prior to imposing sanctions which could have serious consequences for those involved. A range of responses should be considered in terms of proportionate sanctions for breaches, including:

- · employment law action
- reporting incidents to external bodies
- · contractual or legal consequences

Further information on the consequences of breaches and the range of potential sanctions is at <u>annex B</u>.

Organisations should consider whether reports on breaches, the impact of these, and action taken (ie if strong management action or sanctions are taken) should be considered by their governing body, audit committee, executive team or similar on a regular basis.

To aid transparency organisations should consider whether anonymised information on breaches and action taken in response should be prepared and published on websites on a regular basis.

8. Annex A – types of interest

8.1 Financial interest

Where an individual may get direct financial benefits (a benefit may arise from the making of gain or avoiding a loss) from the consequences of a decision their organisation makes. This could include:

- a director (including a non-executive director) or senior employee in another organisation which is doing or is likely to do business with an organisation in receipt of NHS funding
- a shareholder, partner or owner of an organisation which is doing, or is likely to do business with an organisation in receipt of NHS funding
- someone in outside employment
- · someone in receipt of secondary income
- someone in receipt of a grant
- someone in receipt of other payments (eg honoraria, day allowances, travel or subsistence)
- · someone in receipt of research sponsorship

8.2 Non-financial professional interests

Where an individual may obtain a non-financial professional benefit (a benefit may arise from the making of gain or avoiding a loss) from the consequences of a decision their organisation makes, such an increasing their professional reputation or status or promoting their professional career. This could include situations where the individual is:

- an advocate for a particular group of patients
- a clinician with a special interest
- an active member of a particular specialist body
- · undertaking a research role, particularly sponsored research
- an advisor for the Care Quality Commission or National Institute of Health and Care Excellence

8.3 Non-financial personal interests

This is where an individual may benefit (a benefit may arise from the making of gain or avoiding a loss) personally from a decision their organisation makes in ways which are not directly linked to their professional career and do not give risk to a direct financial benefit. This could include, for example, where the individual is:

- a member of a voluntary sector board or has a position of authority within a voluntary sector organisation
- a member of a lobbying or pressure group with an interest in health and care

8.4 Indirect interests

This is where an individual has a close association with another individual who has a financial interest, a non-financial professional interest or a non-financial personal interest who would stand to benefit (a benefit may arise from the making of gain or avoiding a loss) from a decision they are involved in making. This would include:

- close family member and relatives
- · close friends and associates
- business partners

A common-sense approach should be applied to these terms. It would be unrealistic to expect staff to know of all the interests that people in these classes might hold. However, if staff do know of material interests (or could be reasonably expected to know about them) then these should be declared.

9. Annex B - potential sanctions

9.1 Disciplinary sanctions

Staff who fail to disclose any relevant interests or who otherwise breach an organisation's rules and policies relating to the management of conflicts of interest are subject to investigation and, where appropriate, to disciplinary action. This may include:

- employment law action such as:
 - informal action such as reprimand or signposting to training and/or quidance
 - formal action such as formal warning, the requirement for additional training, re-arrangement of duties, redeployment, demotion or dismissal
 - referring incidents to regulators
 - contractual action against organisations or staff
- where the staff member is not a direct employee, review of their appointment to the role that has given rise to the conflict

9.2 Professional regulatory sanctions

Statutorily regulated healthcare professionals who work for, or are engaged by, organisations are under professional duties imposed by their relevant regulator to act appropriately with regard to conflicts of interest. Organisations should consider reporting statutorily regulated healthcare professionals to their regulator if they believe that they have acted improperly, so that these concerns can be investigated. These healthcare professionals should be made aware that the consequences for inappropriate action could include fitness to practise proceedings being brought against them, and that they could, if appropriate be struck off by their professional regulator as a result.

Information and contact details for the healthcare professional regulators are accessible from the <u>Professional Standards Authority for Health and Social Care's website (http://www.professionalstandards.org.uk/what-we-do/our-work-with-regulators/find-a-regulator)</u>.

9.3 Civil sanctions

If conflicts of interest are not effectively managed, organisations could face civil challenges to decisions they make – for instance if interests were not disclosed that were relevant to the bidding for, or performance of contracts. If a decision-maker has a conflict of interest, then the decision is also potentially vulnerable and could be overturned on judicial review. In extreme cases, staff and other individuals could face personal civil liability, for example a claim for misfeasance in public office.

9.4 Criminal sanctions

Failure to manage conflicts of interest could lead to criminal proceedings including for offences such as fraud, bribery and corruption. This could have implications for the organisation concerned and linked organisations, and the individuals who are engaged by them.

The Fraud Act 2006 created a criminal offence of fraud and defines 3 ways of committing it:

- fraud by false representation
- fraud by failing to disclose information
- · fraud by abuse of position.

In these cases, an offender's conduct must be dishonest and their intention must be to make a gain, or a cause a loss (or the risk of a loss) to another. Fraud carries a maximum sentence of 10 years imprisonment and/or a fine and can be committed by a body corporate.

The Bribery Act 2010 makes it easier to tackle this offence in public and private sectors. Bribery is generally defined as giving or offering someone a financial or other advantage to encourage a person to perform certain activities and can be committed by a body corporate.

Commercial organisations (including NHS bodies) will be exposed to criminal liability, punishable by an unlimited fine, for failing to prevent bribery.

The offences of bribing another person or accepting a bribe carry a maximum sentence of 10 years imprisonment and/or a fine. In relation to a body corporate the penalty for these offences is a fine.

9.5 Reputational consequences

A failure to manage conflicts of interest (including the perception of such a failure) can lead to reputational damage and undermine confidence in the integrity of the decision-making process and give the impression that the organisation or individual has not acted in the public interest.

Publication reference: PRN00666

Date published: 17 September, 2024 Date last updated: 17 September, 2024

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